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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,552	08/02/2001	Hideakira Yokoyama	0020-4883P	4627

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EXAMINER	
JAGOE, DONNA A	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 05/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/890,552	YOKOYAMA ET AL.
Examiner	Art Unit	
Donna A. Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM

THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed

- after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-8 and 11-17 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 1-8 and 11-17 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z.

4) Interview Summary (PTO-413) Paper No(s) ____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: ____.

Claims 1-8 and 11-17 are pending in this application.

Information Disclosure Statement

The information disclosure statement filed November 2, 2002 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because there is not an english translation of english language abstract. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Response to Arguments

Rejection of claims 14-16 under 35 U.S.C. § 112 1st paragraph is no longer maintained in view of the amendment.

The Examiner is in agreement with the persuasive remarks submitted concerning the outstanding 35 U.S.C. 112 2nd paragraph rejection in paper number 6 with regard to claims 4-8 in view of which the rejection is hereby withdrawn.

However, the rejection made in paper number 6 over claims 14-16 under 35 U.S.C. § 112 2nd paragraph is maintained and is hereby repeated. While the term "hydrophilic high molecular weight compound" is defined in the specification with regard

to the patch formulation, there is no guidance in the specification with regard to any examples of "hydrophilic high molecular weight compounds" that may be employed with the ointment formulation. It is suggested that the applicant recite a range for example "hydrophilic high molecular weight compounds having a molecular weight of from x to x Daltons".

Applicant's arguments filed February 28, 2002 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102

1. The rejection made in paper number 6 over Yoshida et al. under 35 U.S.C. §102(b) is maintained and is hereby repeated.

Applicant argues that the term "thermogenic sheet-combined poultice" is not a patch and asserts that the invention is not intended for use as a drug. The examiner is not in agreement. The broad definition of the word "patch" is a piece of material. Since a "thermogenic sheet-combined poultice" would still be applied as a "patch", it meets the claim. Applicant further asserts that Yoshida et al. is directed to heat therapy using a thermogenic sheet combined poultice. Applicant does not exclude the use of heat by the broad claim language "*comprising*" which leaves the claim open for the inclusion of unspecified ingredients, even in major amounts and as such, does not exclude thermogenic combined poultice.

2. The rejection made in paper number 6 over Noda et al. under 35 U.S.C. §102(b) is maintained and is hereby repeated.

Applicant asserts that Noda et al. does not teach L-menthol and peppermint oil as an active ingredient for alleviating a migraine. Applicant's claim is drawn to a composition of matter. The intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition.

3. The rejection made in paper number 6 over Block et al. under 35 U.S.C. §102(b) is maintained and is hereby repeated.

Applicant asserts that Block et al. does not teach the active ingredients must be L-menthol and one or more essential oils. In response, "Products of identical chemical composition (i.e. menthol) can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. relief of headaches) are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a *prima facie* case of unpatentability of Spada's polymer latexes for lack of novelty." Applicant asserts that Block et al. teaches that the preferred embodiments contain components other than the

active ingredients claimed in the instant application (l-menthol and one or more essential oils). In response, Block et al. teach, in a preferred embodiment, menthol, and the essential oils, spirits of turpentine, eucalyptus oil and camphor. The humectant is a high molecular weight substance and the thickener is the polyhydric alcohol. Thus Block et al. encompasses the claims of the instant application.

Claim Rejections - 35 USC § 103

1. The rejection made in paper number 6 over Barr et al. under 35 U.S.C. §103(a) is maintained and is hereby repeated.

Applicant asserts that Barr et al. uses capsaicin as an active ingredient and does not use l-menthol as the active ingredient. In response, the claim language *comprising* leaves the claim open for the inclusion of unspecified ingredients, even in major amounts. The claims of the instant application do not exclude capsaicin.

(New) Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Noda et al. U.S. Patent No. 5,519,046.

The claim is drawn to a composition wherein the amounts of l-menthol and one or more essential oils are 0.01%-1% by weight per total weight of the base and 0.001-1% per total weight of the base respectively.

Noda et al. teach menthol in a proportion of from 0.01% to 10% by weight which would encompass the claimed range of the instant claim.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna A. Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on 6:30 A.M. - 3 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 308-7921 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0193.


dj
May 19, 2002

MARIANNE SEIDEL
PRIMARY EXAMINER
GROUP 1600
